PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:	)	
	)	Group Art Unit: 1655
GOLZ *et al.*	)	
	)	Examiner: Bin Shen
Serial No. 10/528,460	)	
	)	Atty Dkt No.: 004974.01083
35 U.S.C. § 371(c) date: December 19, 2005	)	
	)	
Filed: March 18, 2005	)	Confirmation No. 7581

For: **DIAGNOSTICS AND THERAPEUTICS FOR DISEASES ASSOCIATED WITH HUMAN PHOPHODIESTERASE 11A (PDE11A)**

REPLY BRIEF

U.S. Patent and Trademark Office
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Sir:

This Brief responds to the Examiner's Answer. The Answer was mailed November 27, 2007; thus this Brief is timely filed.

STATUS OF THE CLAIMS

Claims 2, 3, and 12-26 are canceled. Claims 1 and 4-11 are pending and are rejected. The rejections of claims 1 and 4-11 are appealed.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

I. Whether claims 1 and 5-9 are anticipated under 35 U.S.C. § 102(b).

II. Whether claims 1 and 4-11 are obvious under 35 U.S.C. § 103(a).

ARGUMENT

Rejection of Claims 1 and 5-9 under 35 U.S.C. § 102(b)

The Examiner's Answer maintained the rejection of claims 1 and 5-9 under 35 U.S.C. § (b) over Yuasa.[1] On page 5, second paragraph of the Answer, the Examiner argues that Yuasa teaches each element of the claimed invention, asserting that Yuasa teaches:

- identification of candidate agents (page 31477, Table II);
- analysis of the tissue-specific expression patterns of human PDE11A (page 31475, Figures 4 and 5); and
- the therapeutic potential of candidate agents in diseases related to different tissues (page 31469, right column, second full paragraph, lines 1-3).

The Examiner has not construed correctly each element of the claimed invention or the teachings of Yuasa.

The steps recited in independent claim 1 are:

(i) contacting a test compound with a PDE11A polypeptide;

(ii) detecting binding **of the same test compound** to said PDE11A polypeptide; and

(iii) identifying **the same test compound** as a candidate therapeutic agent useful in the treatment of any of a group of specific types of disease if the test compound binds to said PDE11A polypeptide.[2]

Table II, page 31477 of Yuasa, which the Examiner asserts teaching "identification of candidate agents" merely summarizes the inhibitory effect of various known PDE inhibitors on human

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[1] Yuasa *et al.*, *J. Biol. Chem. 275*, 31469-79, 2000.

[2] The recited disease types are disorders of the peripheral and central nervous system, cardiovascular diseases, cancer, liver disease, and genitourinary disease.

PDE11A variants. Moreover, Yuasa does not identify any of the agents which bind to PDE11A (PDE inhibitors and cAMP) as candidate therapeutic agents, much less agents for treating any of the specific types of disease recited in independent claim 1. In fact, Yuasa merely speculates:

- "Novel PDEs **may** also be valuable as pharmacologically significant targets" (Yuasa, page 31462, col. 2, second full paragraph, emphasis added); and
- "each PDE plays a distinct physiological role in different tissues and cells and **may** be valuable pharmacological targets." Yuasa, page 31469, right column, second full paragraph (emphasis added).

Moreover, Yuasa's teaching in the paragraph bridging pages 31478 and 31479 that "[p]harmacological analysis using selective inhibitors for this enzyme **will elucidate new physiological functions** of cAMP or cGMP in prostate and testis" (emphasis added) is in fact a teaching that Yuasa does not know that test compounds which bind to PDE11A are candidate therapeutic agents for the treatment the specific types of diseases recited in claim 1.

On page 5, second paragraph of the Answer, the Examiner contends that Yuasa's disclosure of tissue-specific patterns of PDE11A mRNA is the equivalent of Appellants' teaching of PDE11A's specific pharmacological utilities. Even having this information, however, Yuasa does not even speculate about the role PDE11A may play as a therapeutic target.

In the paragraph bridging pages 5 and 6 of the Answer, the Examiner contends: "Furthermore, a method of screening for candidate therapeutic agents is [sic; as?] claimed [is] not a method of treatment of diseases." In the same paragraph, the Examiner faults the specification because it does not describe "method/steps of administration of candidate agent[s] to treat the examined species of cardiovascular disease . . .." Claim 1 does not require treatment of a disease. Claim 1 is directed to a screening method for potential pharmacologic agents. It is

improper for the Examiner to imply that Appellants must teach and claim a method of treatment to distinguish the claimed methods from Yuasa.

In summary, Yuasa does not explicitly teach each element of independent claim 1. Nor does Yuasa inherently teach each element of claim 1. It is black letter law that to establish inherency, extrinsic evidence "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 U.S.P.Q.2d 1746, 1759 (Fed. Cir. 1991). The skilled worker would not recognize in Yuasa a teaching that any of the disclosed agents could be tested for their potential use as therapeutics for the types of diseases recited in claim 1.

Rejection of Claims 1 and 4-11 Under 35 U.S.C. § 103(a)

The Examiner's Answer also maintained the rejection of claims 1 and 4-11 under 35 U.S.C. § 103(a), in which Lanfear[3] is added to Yuasa to reject claims 1 and 4-11 as *prima facie* obvious. As explained on page 8 of the Brief on Appeal, the analysis is simple. Yuasa does not teach or suggest step (iii) of independent claim 1. Lanfear also does not teach or suggest this step. The combination of Yuasa and Lanfear does not teach each element of claim 1. Claims 1 and 4-11 are therefore not *prima facie* obvious over the cited combination.

Respectfully submitted,

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Date: January 27, 2008

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[3] Lanfear *et al.*, US 2002/0115176.